

REMARKS

Claims 1, 4-15, 21-24, 26 and 28-29 remain pending, and new claims 30-39 have been added in the subject application. Based on the following remarks, reconsideration and allowance of the application are respectfully requested.

As a preliminary matter, Applicants wish to thank the Examiner for taking the time to discuss the application claims and cited prior art references with the undersigned representative on September 15, 2008. The amendments made to the claims in this paper are a direct result of the conversation in an effort to bring the application into condition for allowance.

Double Patenting Rejection

Claims 1, 4-15, 21-24, 26 and 28-29 stand rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 13-33 of co-pending Application No. 10/866,428. Applicants respectfully traverse this rejection, since claims 13-33 of co-pending Application No. 10/866,428 are directed to a method of qualifying an automated biological screening system, and to a method of generating statistical information for a biological specimen, whereas the claims of the present application are directed to an automated method of classifying a cytological sample, including the attachment of a respective “positive” or “manipulation” designator as part of the automated method, and which is not disclosed or suggested in Application No. 10/866,428 (See further discussion below in conjunction with the rejections under 35 USC 102(e)). Further, the Examiner has not set forth any description of the requisite factual inquiries that must be employed when making an obvious-type double patenting analysis (see MPEP §804), and as such the Applicants are unable to respond with any greater specificity.

Thus, Applicants respectfully request reconsideration and withdrawal of the double patenting rejection.

Rejections under 35 U.S.C. § 102

Zahniser

Claims 1, 22, 24 and 26-29 stand rejected under 35 U.S.C. § 102(b) for allegedly being anticipated by USP 5,168,066 (“Zahniser”). In order to sustain a rejection under §102, each element in the rejected claim must be found, either expressly or inherently, in the cited reference. Applicants respectfully traverse this rejection, since Zahniser does not disclose each and every element required by these claims.

In particular, claim 1 has been amended to more specifically recite that the positive designator designates the sample as satisfactory *for preparing a specimen slide from the sample*; and the manipulation designator designates the sample as requiring a manipulation *to render the sample adequate for slide preparation*. (Emphasis Added). Claims 4-15, 21-24, 26 and 28-29 depend from claim 1, and thus include the same limitations. Zahniser does not teach attaching a positive designator to the sample vessel if the sample is satisfactory for preparing a specimen slide from the sample, or attaching a manipulation designator to the sample vessel if a manipulation is required in order to prepare a specimen slide from the sample.

The Examiner states that the claimed attachment of positive and manipulation designators may be read on the steps of recording the image and comparison to certain parameters to obtain a diagnosis taught by Zahniser. Applicants respectfully submit that this reading is contrary to the teachings of the specification, in view of which the application claims must be read. As discussed in the specification at p. 13, line 24 through p. 14, line 3, the designators can be physically or electronically attached to the sample vessel. Zahniser's recording of the image does not fall within this definition of a designator.

In addition to not teaching a designator at all, Zahniser further does not teach attaching a designator *after* the step of determining whether a result of the optical interrogation meets a criterion. Independent claim 1 recites that a positive designator is attached if the result meets the criterion and a manipulation designator is attached if the result does not meet the criterion. Clearly, the claim requires that the step of determining whether the result meets the criterion must occur before attaching a designator since the decision of which designator to attach is based on whether the results meet the criterion. The Examiner states that the acts of (i) recording an image, and (ii) making a comparison with certain parameters to obtain a diagnosis, taught in Zahniser somehow read on the claimed acts of attaching a positive designator and attaching a manipulation designator steps. However, nowhere does Zahniser teach that a determination of whether a result meets a criterion occurs *before* attaching a designator, let alone a designator relating to whether a specimen slide may be prepared from the sample without further manipulation.

For at least these reasons, Applicants respectfully submit that independent claim 1, along with those rejected claims which depend therefrom, are not anticipated by Zahniser, and respectfully request reconsideration and withdrawal of the claim rejections under 35 U.S.C. § 102(b) based on Zahniser.

Bukshpan

Claims 1, 15, 22, 24, 26 and 28-29 stand rejected under 35 U.S.C. § 102(e) for allegedly being anticipated by US 2002/0198928 (“Bukshpan”). In order to sustain a rejection under §102, each element in the rejected claim must be found, either expressly or inherently, in the cited reference. Applicants respectfully traverse this rejection, since Bukshpan does not disclose each and every element required by these claims.

Like Zahniser, Bukshpan does not teach attaching a positive designator to the sample vessel or attaching a manipulation designator to the sample vessel. The Examiner states that the claimed attachment of positive and manipulation designators may be read on the steps of recording an image and making a comparison to certain parameters to obtain a diagnosis, as taught by Bukshpan. Applicants respectfully submit that this reading is contrary to the teachings of the specification, in view of which the claims of the application must be read. As discussed in the specification at p. 13, line 24 through p. 14, line 3, the designators can be physically or electronically attached to the sample vessel. Bukshpan’s recording of the image does not fall within this definition of a designator.

In addition to not teaching a designator at all, Bukshpan further does not teach attaching a designator *after* the step of determining whether a result of the optical interrogation meets a criterion. Independent claim 1 recites that a positive designator is attached if the result meets the criterion and a manipulation designator is attached if the result does not meet the criterion. Clearly, claim 1 requires that a determination of whether the result meets the criterion must occur *before* attaching a respective positive or manipulation designator to the sample vessel, since a decision of which designator to attach is based on whether the results meet the criterion. Again, the Examiner states that recording an image and making a comparison to certain parameters to obtain a diagnosis reads on the claimed “attaching a positive designator” and “attaching a manipulation designator”. However, nowhere does Bukshpan teach that a step of determining whether a result meets a criterion occurs *before* a step of attaching a designator.

Moreover, like Zahniser, Bukshpan does not teach attaching a designator *to the sample vessel*, and nowhere in the record has the Examiner specified where in Bukshpan the act of attaching a designator *to the sample vessel* is supposedly found.

Further, Bukshpan does not teach or suggest that the positive designator designates the sample as satisfactory *for preparing a specimen slide from the sample*; and the manipulation

designator designates the sample as requiring a manipulation *to render the sample adequate for slide preparation*. (Emphasis added).

For at least these reasons, Applicants respectfully submit that independent claim 1, along with those rejected claims which depend therefrom, are not anticipated by Bukshpan, and respectfully request reconsideration and withdrawal of the claim rejections under 35 U.S.C. § 102(e) based on Bukshpan.

Isenstein

Claims 1, 4-15, 21-24, 26 and 28-29 stand rejected under 35 U.S.C. § 102(e) for allegedly being anticipated by US 2004/0253144 (“Isenstein”). In order to sustain a rejection under §102, each element in the rejected claim must be found, either expressly or inherently, in the cited reference. Applicants respectfully traverse this rejection, since Isenstein does not disclose each and every element required by these claims.

In fact, Applicants submit that Isenstein does not teach *any* of the actions set forth in independent claim 1, and it is not at all apparent to the Applicants why/how Isenstein is being used by the Examiner for making the rejections. The Examiner simply states that “Figures 5-12 teach various decision trees that encompass the claimed automated method of classifying and analyzing the samples.” However, Isenstein actually teaches a method for qualifying an automated biological screening system to ensure that it consistently provides accurate results in identifying the most pertinent biological objects for subsequent review by a technician, which is not at all similar to the claimed method of classifying a cytological sample. Thus, Applicants respectfully submit that it is unclear which of the acts taught by Isenstein are believed to anticipate the claimed acts, and nowhere in the record has the Examiner specified where in Isenstein the claimed acts are supposedly found.

Claim 1 recites attaching a positive designator to the sample vessel or attaching a manipulation designator to the sample vessel. Isenstein does not teach attaching a positive designator to the sample vessel or attaching a manipulation designator to the sample vessel, and nowhere in the record has the Examiner specified where in Isenstein the act of attaching a designator to the sample vessel is supposedly found.

In particular, Isenstein does not teach or suggest that the positive designator designates the sample as satisfactory *for preparing a specimen slide from the sample*; and the manipulation

designator designates the sample as requiring a manipulation *to render the sample adequate for slide preparation*. (Emphasis added).

For at least these reasons, Applicants respectfully submit that independent claim 1, along with the remaining claims which depend therefrom, are not anticipated by Isenstein, and respectfully request reconsideration and withdrawal of the claim rejections under 35 U.S.C. § 102(e) based on Isenstein.

Rejections under 35 U.S.C. § 103

Claims 4-14 stand rejected under 35 U.S.C. § 103(a) for allegedly being obvious over Zahniser or Bukshpan in view of USP 6,629,057 (“Zweig”). Applicants respectfully traverse this rejection, since no combination of Zahniser and Zweig or Bukshpan and Zweig discloses, teaches, or suggests the combination of elements required by these claims.

In particular, as discussed above, Zahniser and Bukshpan do not teach or suggest several elements of independent claim 1, from which claims 4-14, 21 and 23 depend. For example, Zahniser Bukshpan, alone or in combination, do not teach or suggest attaching a positive or manipulation designator to the sample vessel after determining whether a result of an optical interrogation meets a criterion. Nor do Zahniser Bukshpan, alone or in combination, teach or suggest that the positive designator designates the sample as satisfactory *for preparing a specimen slide from the sample*; and the manipulation designator designates the sample as requiring a manipulation *to render the sample adequate for slide preparation*. (Emphasis added). Zweig does not supplement this deficiency in Zahniser and Bukshpan.

Nor does Zweig teach or suggest that the sample meets the criterion if it contains a sufficient quantity of cellular matter for performing a diagnostic evaluation of the specimen slide, as required by claims 4 and 5; that the positive designator indicates that the sample is satisfactory for automated slide preparation, as required by claim 6; that the positive designator indicates that the sample is adequate in quantity to allow for withdrawal of a portion of the sample sufficient for performing a diagnostic evaluation of the specimen slide, as required by claim 7, that the manipulation designator indicates that acquisition of additional cellular matter in the sample is needed for performing a diagnostic evaluation of the specimen slide, as required by claim 8; that the manipulation designator indicates that treatment of the sample is needed prior to performing a diagnostic evaluation of the specimen slide, as required by claims 9-11; that the criterion is a concentration of cells in the sample, as required by claims 12-14; or that the

positive or manipulation designators may comprises a physical marking on the vessel, as required by respective claims 21 and 23.

Thus, Applicants submit that claims 4-14, 21 and 23 are not obvious over any proper combination of Zahniser and Zweig or Bukshpan and Zweig, and as such, respectfully request withdrawal of the §103 rejection of these claims.

New claims 30-39

New independent claim 30 includes “determining, based on the interrogation, *whether the sample has an adequate concentration of cellular matter needed for performing an intended assay*; associating a positive designator with the sample if the sample has *an adequate concentration of cellular matter for performing the intended assay*; and associating a manipulation designator with the sample if the sample *does not have an adequate concentration of cells to perform the intended assay*[.]” (Emphasis added). Claim 30 also recites that “performance of the intended assay comprising preparing a specimen slide from said sample, and performing a diagnostic review of the specimen slide.” Claims 31-34 depend from claim 30, and thus include the same limitations.

New independent claim 35 includes “associating a positive designator with the sample if the result meets the criterion, wherein the positive designator designates the sample as satisfactory for *performing an assay to detect the presence or absence of human papilloma virus*; and associating a manipulation designator with the sample if the result does not meet the criterion, wherein the manipulation designator designates the sample as requiring a manipulation to render the sample adequate before the assay can be performed.” (Emphasis added). Claims 36-39 depend from claim 35, and thus include the same limitations.

It is respectively submitted that none of the cited prior references of record teach or suggest these limitations.

Information Disclosure Statement filed July 16, 2008

The Applicants wish to bring the references cited in the IDS filed July 16, 2008 to the Examiner's attention.

CONCLUSION

Based on the foregoing remarks, Applicants respectfully submit that the pending claims are now allowable over the cited references. Applicants invite the Examiner to call the undersigned if any remaining issue(s) can be resolved through a telephonic discussion.

Respectfully submitted,
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